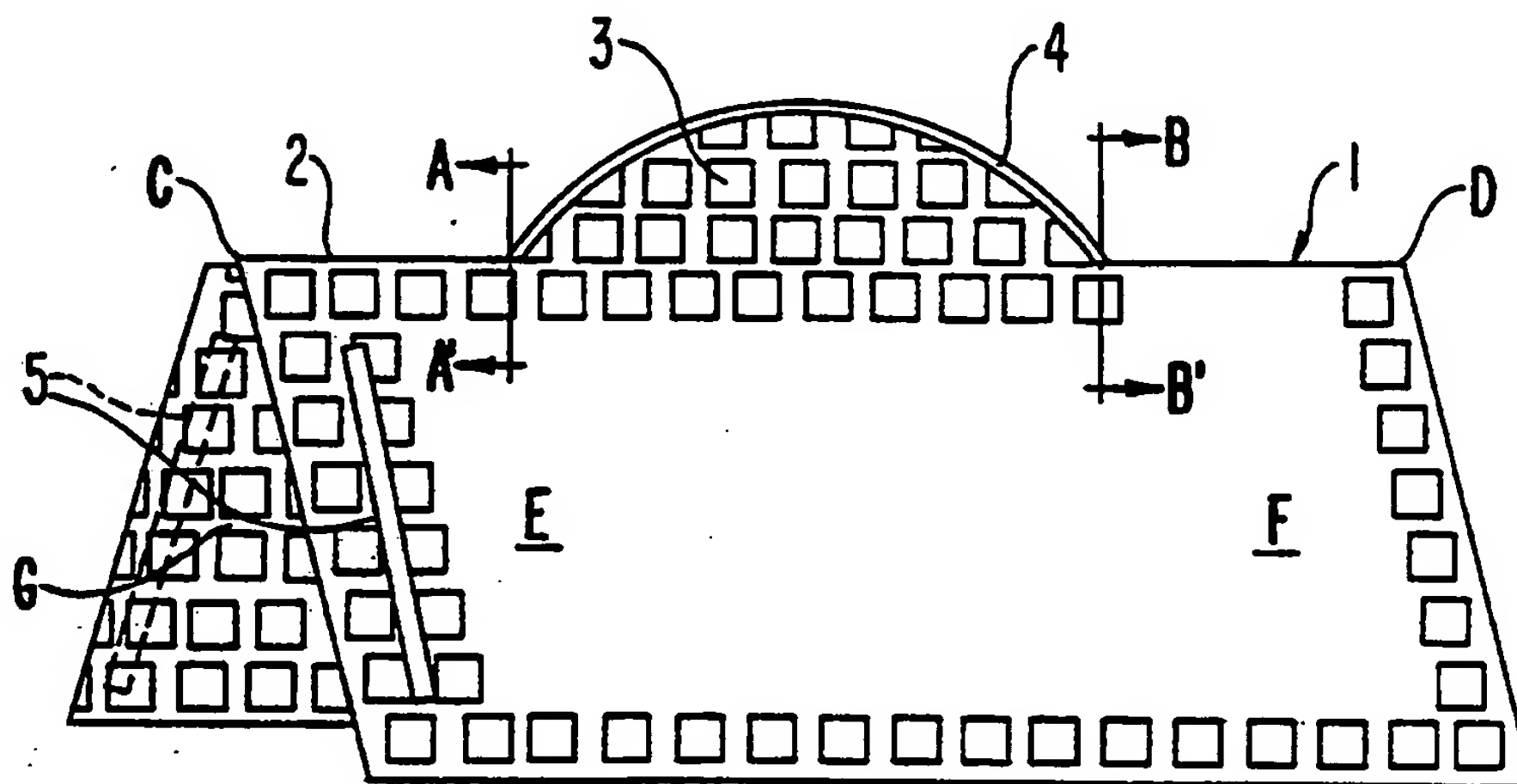




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(21) International Application Number: PCT/US92/10051 (22) International Filing Date: 17 November 1992 (17.11.92) (30) Priority data: 798,682 26 November 1991 (26.11.91) US (71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US). (72) Inventor: NORVELL, Jean ; 30 Park Drive, Newark, DE 19713 (US). (74) Agents: SAMUELS, Gary, A. et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).		(81) Designated States: AU, CA, DE, GB, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: ADJUSTABLE ONE-PIECE WATERPROOF PADDED CAST LINER**(57) Abstract**

An adjustable one-piece water-vapor transmitting padded (15) liner for an orthopedic cast, including a hydrophilic water-vapor transmitting polymer (13) layered with a hydrophobic polymer membrane (14) to protect the skin under the cast.

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TITLE OF THE INVENTION

ADJUSTABLE ONE-PIECE WATERPROOF PADDED CAST LINER

FIELD OF THE INVENTION

5 The invention relates to protective padding which provides cushioning and padding underlying an immobilizing orthopedic cast to protect the skin of the wearer during the time the cast must remain in place on the body member being treated.

BACKGROUND OF THE INVENTION

10 In applying a conventional plaster-of-paris cast, it is standard practice to first cover the body member being treated with a protective cloth bandage or wrap, such as cotton or polyester knit fabric. The protective cloth-covered body member is then covered with cotton or polyester padding to provide a soft resilient padded protective liner. This padding is then
15 overwrapped with a form of wetted plaster-of-paris wrapping of sufficient length and to such a thickness as to provide an immobilizing structure of adequate strength and durability.

It is also known to make casts from glass fiber materials, which consist of heat-softened or curable organic polymeric resins
20 coated on glass fibers which have been woven into fabrics or are formed into unwoven open fibrous mats. Such flexible coated glass fabrics are wrapped while warm about a bodymember to be immobilized in much the same manner as plaster-containing cloth and allowed to cool and harden after the cast is formed, such as in U.S. Patent
25 3,882,827 and resin/glass fiber composites described in U.S. Patents 4,273,115 and 4,238,522.

While the conventional plaster-of-paris casting system and the glass fiber casting system are in widespread use, they have several disadvantages. A plaster cast is considered to be non-breathable
30 and must be kept dry inside the cast since it cannot breathe.

While glass fiber casts themselves are impervious to water and

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not affected by immersion in water, the skin is wet under the cast. A lack of air to dry the skin could permit maceration of the skin under the cast, thus opening it to attack by bacteria.

5 An additional problem with many casts is that odor develops owing to retention of perspiration and body oils in the cast. As the body secretions or wound drainage are absorbed into the cast padding and ultimately into the cast itself, it may generate a very foul odor. This may become so objectionable as to require a complete change of cast. Deodorants are available for
10 incorporation into the cast material or padding at the time of application, but these have generally proven to be ineffective and most are no longer in use.

Skin erosion and subsequently formed pustules that emanate from blocked hair follicles may cause extreme itching and
15 discomfort for a patient wearing a conventional cast. Additionally, urine soaked casts, particularly in the case of Spica casts worn by infants for several months at a time, have wet padding in constant touch with the skin and therefore unable to dry, resulting often in ulcerated areas on the skin.

20

BRIEF DESCRIPTION OF THE INVENTION

The present invention provides a liner for an immobilizing orthopedic cast which allows the skin under the cast to remain relatively clean and undamaged despite being under the cast for a prolonged time period. The liner transmits water vapor,
25 perspiration or urine away from the skin under the liner and cast.

The liner of the invention comprises an adjustable one-piece waterproof padded cast liner in which an inner layer of waterproof water vapor-transmitting polymer material is affixed to or encloses a layer of padding material. Adhesive strips are affixed to
30 selected locations on the liner to attach to each other segments of the liner after the segments are folded to fit closely around the body member upon which the cast is being formed. The liner is configured to closely fit and enclose the body member upon which the cast is being formed, particularly around angular body parts,
35 such as elbows and ankles, for example.

Since removal of a cast is ordinarily done by cutting the cast with an oscillating saw, for example, the operator of the saw must be aware of reaching skin level beneath the cast. Otherwise, burns, cuts and abrasions of the skin may occur. To aid in a comfortable, safe cutting process, adhesive strips may be affixed to the liner at locations normally selected for cutting the cast for its removal, such as along the inside edge of an arm and elbow, or a leg, ankle, and foot. The strips provide perceptible resistance to a cutting edge of a cast-removal device. On the outside surface of the adhesive strips is coated a layer of surface-textured material, such as the ridges and grooves of corrugation, fibrous netting, entangled fibers, grit, and cut and abrasion resistant polymer, for example.

A preferred waterproof water-vapor transmitting polymer material comprises an expanded polytetrafluoroethylene (PTFE) membrane which has an attached contiguous layer of hydrophilic water vapor-transmitting polymer, such as a hydrophilic polyurethane. This two-layer material may be attached to a layer of padding material or two layers may surround the padding material.

Other hydrophobic polymers may be used instead of PTFE and other contiguous layers of hydrophilic polymers may be attached to it instead of polyurethane so long as they have useful ranges of water vapor-transmission along with oleophobic properties, which prevent the transmission of body oils to the PTFE layer which will then lose its waterproof properties if penetrated by oily material.

The padding of the invention preferably requires that an outer waterproof layer must have a hydrophilic layer between it and the body skin to remain functional during the period that it lines an orthopedic cast to prevent loss of waterproofness. Thus a two-layer cast liner wherein a layer of the hydrophobic/hydrophilic material surrounds and is bonded at intervals around padding to resemble a waffle pattern, such as a textile fabric or fiber scrim material, has at least one water-vapor transmitting oil blocking layer between the skin and the waterproof water-vapor transmitting hydrophobic polymer material, such as expanded PTFE.

Two layers of hydrophilic polyurethane material surrounding the padding may also be used in the present invention, in that

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these layers may be sufficiently waterproof to be adequately functional in the invention.

5 A one-piece liner of the invention comprises a shaped single sheet of padded membrane configured to be folded around a body member with minimum overlap of liner material. The single sheet may also comprise more than one piece of liner material bonded together at the edges with heat and pressure, an adhesive or by sewing them together with straight or zigzag stitching to form a single sheet of liner which must be folded to lie flat, but when
10 unfolded forms a pocket which fits easily, smoothly, and with minimum overlap around a body member, such as an ankle and foot, an elbow, an elbow, arm, and hand together, or the lower trunk and hip area, such as is covered by a Spica cast in infants. The one-piece liner may be easily trimmed to size at the time of application to a
15 body member and several sizes may be supplied to keep trimming to size to a minimum. Trimming includes cutting some of the bonded area to aid in achieving proper fit when the liner is folded about an ankle and foot for instance. If the liner is manufactured so that the padding is broken up into cells by bonding lines in
20 between cells, trimming to size preferably is done between cells and rows of cells so that fibers of padding are not exposed in the cut line.

BRIEF DESCRIPTION OF THE DRAWINGS

25 Figure 1 is a folded one-piece liner configured for fitting around an ankle and foot under a cast, the padding therein being divided into cells by bond lines.

Figure 1A is a liner of Figure 1 partially enclosing a foot and ankle.

30 Figure 2 is a folded one-piece liner configured for enclosing an elbow, arm, and hand under a cast.

Figure 2A is a liner of Figure 2 partially surrounding an elbow, arm, and hand in position for closure.

Figure 3 is a one-piece liner configured for use under a Spica cast.

35 Figure 3A is a liner of Figure 3 in place around an infant

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before application of a Spica cast.

Figure 4 is a perspective cross-section of a liner material useful in the invention.

Figure 5 is a cross-sectional view of a segment of liner useful in the invention in which the padding is divided into cells.

Figure 6 is a cross-sectional view of a segment of a liner material useful in the invention wherein the hydrophilic layer and hydrophobic layers are reversed from their position in Figure 5.

Figure 7 is a cross-sectional view of a segment of an liner material useful in the invention wherein two hydrophilic layers surround the padding.

Figure 8 is a perspective view of a closed liner having adhered to its outside surface a strip of cut-resistant tape.

DETAILED DESCRIPTION OF THE INVENTION

A detailed description of the invention is now provided in terms of the drawings to more carefully describe the invention, materials used in its manufacture, details of manufacture, and methods for applying the liner of the invention to body members upon which an orthopedic cast is to be applied.

A preferred form of liner includes a porous membrane of a liquid water impenetrable, water vapor permeable organic polymeric membrane, preferably of microporous expanded polytetrafluoroethylene. This membrane is characterized by properties which permit water, perspiration, or urine to vaporize away from the skin through the membrane by moisture vapor transmission so that the skin remains dry. The membrane has no air permeability. The membrane has attached to it a continuous hydrophilic layer that transports water by an absorption-evaporation mechanism, such as a hydrophilic polyurethane layer for example. The hydrophilic layer is attached to the microporous hydrophobic membrane layer which permits no detectable passage of liquid water. Any known membrane having the requisite properties may be used for this layer of the cast of this invention, although the preferred materials are the microporous expanded polytetrafluoroethylene membranes described in U.S. Patent Nos.

4,194,041 and 4,443,511. Also utilizable are microporous polypropylene films and polyurethane films and tightly woven fabrics of polyolefin fibers and polytetrafluoroethylene and other fluorinated polymer fibers.

5 Breathability of the liner is achieved by evaporation of water inside the inner surface of the membrane, followed by gaseous diffusion of water vapor through the membrane to the outside. This ensures that the surface of the skin remains dry, thus guarding against skin maceration and irritation. The membrane serves to
10 deter bacterial development, since it is a natural barrier to bacteria which cannot pass through pores of such small size. Also, the membrane has no nutritive substance for bacteria to feed upon. Thus, odor caused by rampant bacterial growth on moist skin unable to dry will not occur. Body secretions or wound drainage cannot
15 seep into padding or ultimately into the cast itself. Therefore, odor is greatly reduced.

Figure 1 describes a one-piece liner 1 of the invention which is configured for lining an orthopedic cast around an ankle and foot. Liner 1 is illustrated as being divided into cells 3 of
20 padding surrounded by bond lines where the outer layers of the liner have been adhered to each other around specified portions of the padding. Liner 1 is formed by sealing two pieces of the liner material together by heat and pressure, by other means of adhesion, or by sewing along edge 4, leaving portions A,A to C, and D to B,
25 B' unsealed. When the two layers of liner partially sealed together on an edge portion are spread apart, the liner automatically opens to form a pocket suitable for enclosing a heel or an elbow. Strips of self-sealing pressure sensitive adhesive 5 are applied to the liner at appropriate locations to hold together
30 the parts of the liner around an ankle and foot. Adhesive strips 5 usually have a non-sticking removable cover strip adhered to their outer surface. The cover sheet is removed during fitting of the liner to the foot and ankle to leave the adherent surface of the adhesive strip capable of adhering to a surface which touches it,
35 in this case a flap of the liner.

In Figure 1A, liner 1 is opened up to form a heel pocket at edge 4 which is wrapped around a foot 6 and ankle 2, flap F folded over flap E around the ankle 4 and flap H folded over flap G around

the foot 6. Edge 2 can be lengthened by slitting bond line 4 such that the flaps fit better around the foot and ankle. The edge of the flaps E, F, G, and H may be trimmed for less overlap and better fit. The liner may also be supplied in several sizes to also aid in rapid proper fitting. Adhesive strips 5 hold the folded over flaps in place on each other. A plaster or glass fiber/polymer cast can now be applied over the liner surrounding the ankle and foot.

The liner shown in Figure 2 is similar to that of Figure 1, but has one side longer than the other to fit an elbow, arm, and hand. Sealed edge 4 holds two pieces of liner together which lie flat when not being used. Non-sealed edges 2 aid in forming flaps E, F, G, and H which fold about an upper arm and a lower arm, wrist, and hand when the liner is opened up to create an elbow pocket along edge 4. A shaped segment has been removed to leave cut-out 8 to fit around a thumb.

Figure 2A shows a liner in place around an elbow, ready to be folded over an upper arm, lower arm, wrist, and hand to form the cast liner. Again, as for the liner of Figure 1, the liner of Figure 2 may be trimmed along flaps E and H to slightly overlap flaps F and G and adhesive strips 5. Sealed edge 4 may be shortened if necessary to achieve a closer, better fitting liner.

Figure 3 illustrates a liner designed for fitting around an infant in the areas covered by a Spica cast. Figure 3A shows this liner fitted around an infant to leave area 12 open such that body functions of the infant do not affect the liner and cast applied over the liner and the infant, cast, and liner may be more easily kept clean during the time the cast must be in place on the infant.

Figure 4 is a segment of liner useful in the invention wherein padding layer 15 adheres to one side of waterproof hydrophobic porous membrane 14 and hydrophilic water vapor-transmitting polymer layer 13 is affixed to the other side thereof. Padding layer 15 may be any padding material known to be useful underlying an orthopedic cast, such as woven or unwoven material or synthetic textile fiber cloths and scrim of cotton, polyester, wool, polyamide, or a polymer foam, for example. Heat, pressure, or adhesive bonding may be used. Hydrophilic layer 13 may be a polyether polyurethane, a perfluorosulfonic acid having hydrophilic

side groups, such as a Nafion® (E. I. DuPont de Nemours & Co.), or polyether, polyglycol polymer, or polyhydroxy acid polymers which transport water vapor through their thickness by an absorption evaporation mechanism.

5 Figure 5 shows two segments of liner in which cells of padding 15 are enclosed by two layers of hydrophobic membrane 14 and hydrophilic polymer 13 which have been pressed together to form the cells in a regular, close-spaced pattern. Hydrophilic polymer layer 13 lies on the outside of hydrophobic polymer membrane layer 14 to lie against the skin under the cast to prevent body oils from
10 penetrating the padding to reduce the waterproof property of membrane layer 14. This phenomenon has been fully described in U.S. Patent 4,194,041.

15 It has also been found that in some instances, layers 13 and 14 may be reversed from the relationship shown in Figure 5 and may be utilized without disadvantage as shown in Figure 6. Their being two sets of hydrophobic/hydrophilic layers arranged as shown in figure 6 leaves at least one hydrophilic layer in position to block the penetration of body oils into at least one layer of hydrophobic
20 polymer.

25 Figure 7 describes a liner made up solely of two hydrophilic layers 13 surrounding padding 15. Some hydrophilic materials have been shown to be sufficiently waterproof as well as water vapor-transmitting so as to be adequate for use in protecting the skin by an under-cast liner in some instances.

30 Figure 8 describes a liner suitable for underlaying an elbow cast in which the liner has been folded closely about the area to be covered by the cast, flap E being folded over flap F and held in place by adhesive strip 5, and flap G folded over flap H and similarly held in place by an adhesive strip 5. Adhesive strip 16 is adhered to the outside of the liner along a line on the inside of liner which is usually followed on cutting through the cast outside the liner for its removal. Adhesive strip 16 is coated on its outside surface with material which provides perceptible
35 resistance to cutting or abrasion, so that an operator cutting the cast would instantly notice a dragging or vibration of the cutting edge and be aware thus that the cut had fully penetrated the cast. A surface texture, a grit, or fibers can serve to provide such

cutting resistance. For clarity, the lines of a cell structured padding are not shown.

5 For a spica cast patient using materials presently known in the art, the baby cannot be immersed for bathing since the padding would become wet. However, if the padding is encapsulated for protection as in the invention, immersion can be used for bathing if the casting material used is glass fiber/polymer, which will not hold or be deteriorated by water (a plaster of paris cast will soften and/or crack in water).

I CLAIM:

1. An adjustable one-piece waterproof padded orthopedic cast liner comprising:
 - (a) a layer of water vapor-transmitting polymer material enclosing a layer of padding material; and
 - (b) means for attaching to each other segments of said liner after folding said segments to fit closely around the body member upon which the cast is being formed;
 - (c) said liner being configured to closely fit and enclose a body member upon which a cast is being formed.
2. A liner of Claim 1, wherein said one-piece liner is formed from two layers of liner, each layer having at least one curved edge, said layers of liner being sealed together along a portion of each said curved edge such that when said layers are spread apart, said liner opens to form a pocket suitable for enclosing a heel or elbow.
3. A liner of Claim 1, wherein said waterproof water-vapor transmitting polymer is selected from the group expanded polytetrafluoroethylene, porous polypropylene, polyurethane, and fluorinated polymers, tightly woven hydrophobic textile fiber cloth of polyolefin, polytetrafluoroethylene, and fluorinated polymers.
4. A liner of Claim 1, wherein said means for attaching to each other said liner segments comprises adhesive strips.
5. A liner of Claim 2, wherein said polymer layer is coated with a hydrophilic water-vapor transmitting material.
6. A liner of Claim 3, wherein said hydrophilic material is selected from the group polyurethane polymer, a fluorinated sulfonic acid copolymer with tetrafluoroethylene, polyether polymer, epoxy polymer, hydroxy acid polymer, and polyether polyurethane polymer.
7. A liner of Claim 1, wherein said adhesive strips comprise contact adhesive.
8. A liner of Claim 5, wherein said adhesive strips are covered with an easily peelable non-adhesive cover strip.
9. A liner of Claim 1, wherein said padding material is selected from the group woven or unwoven natural and synthetic textile fiber fabrics and scrims and polymer foams.

10. A liner of Claim 1, wherein said padding material is selected from the group cotton, polyester, wool, polyamide, acetate, and polyolefin, fiber, and polymer foam.
- 5 11. An assembly of a liner of Claim 1 with a plaster or polymer/fiber orthopedic cast.
12. A fitted orthopedic cast liner intended to serve as a padding between an orthopedic cast and an angular body part, comprising a layer of padding material having laminated to each side thereof a layer of liquid water impermeable, water vapor permeable film thereby creating a liquid water impermeable, water vapor permeable padding, wherein said
10 water impermeable, water vapor permeable padding is cut into a pattern having edges and formed into a shape suitable for enclosing angular body parts, said shape further having a first portion of the edges overlapping a second portion of the edges.
15
13. A fitted orthopedic cast liner according to Claim 11, wherein the overlapping edges are taped together.
14. A liner of Claim 1 bearing on its outer surface an adhesive
20 strip, the outer surface of which includes a coating which provides perceptible resistance to a cutting edge of a cast-removal device.
15. A liner of Claim 13, wherein the coating on said strip is selected from the group consisting essentially of surface-
25 textured material, corrugated material, fibrous netting, tangled fibers, woven fibers, particulate material, grit, and cut and abrasion-resistant polymer

FIG. 1

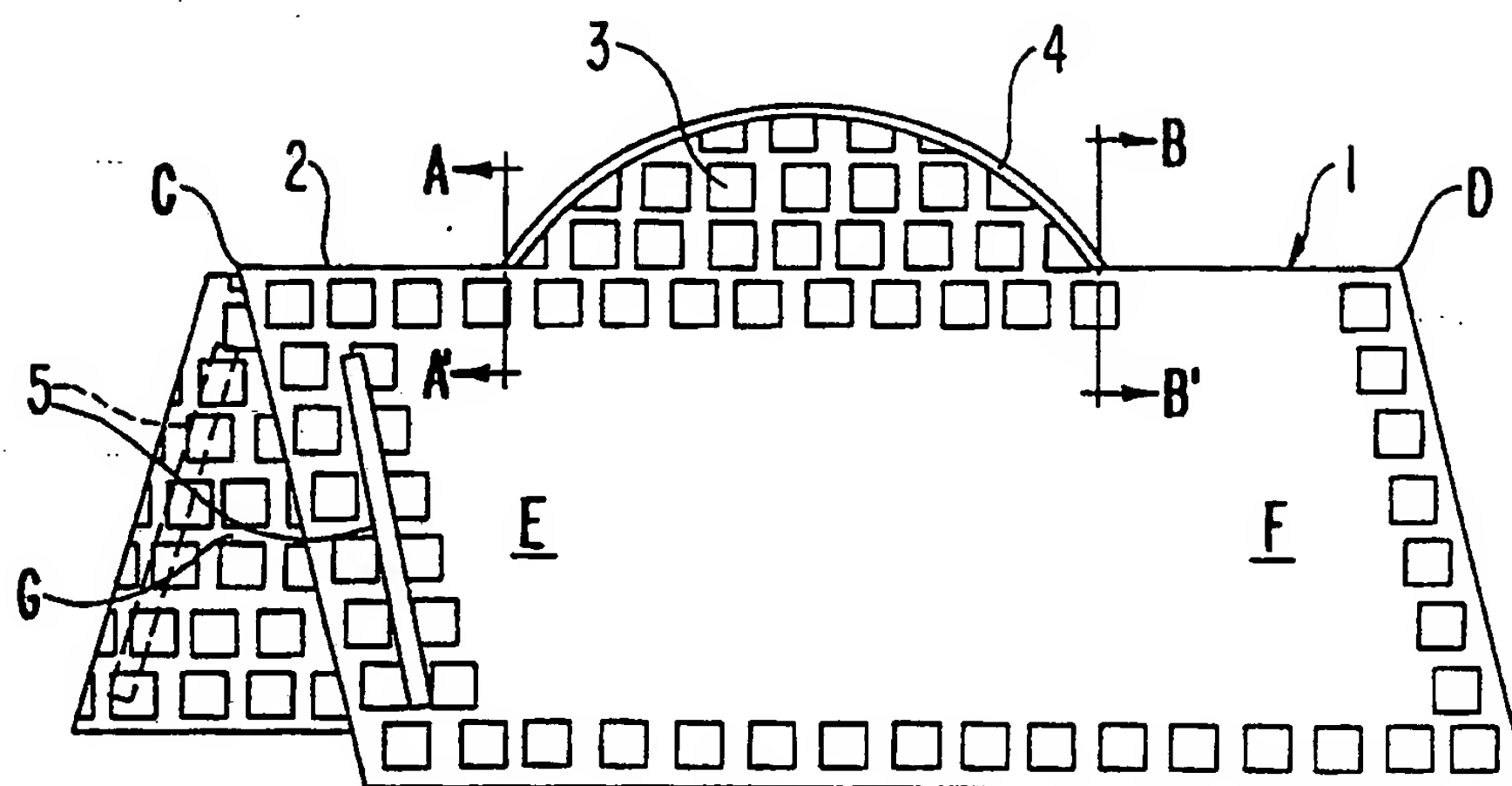
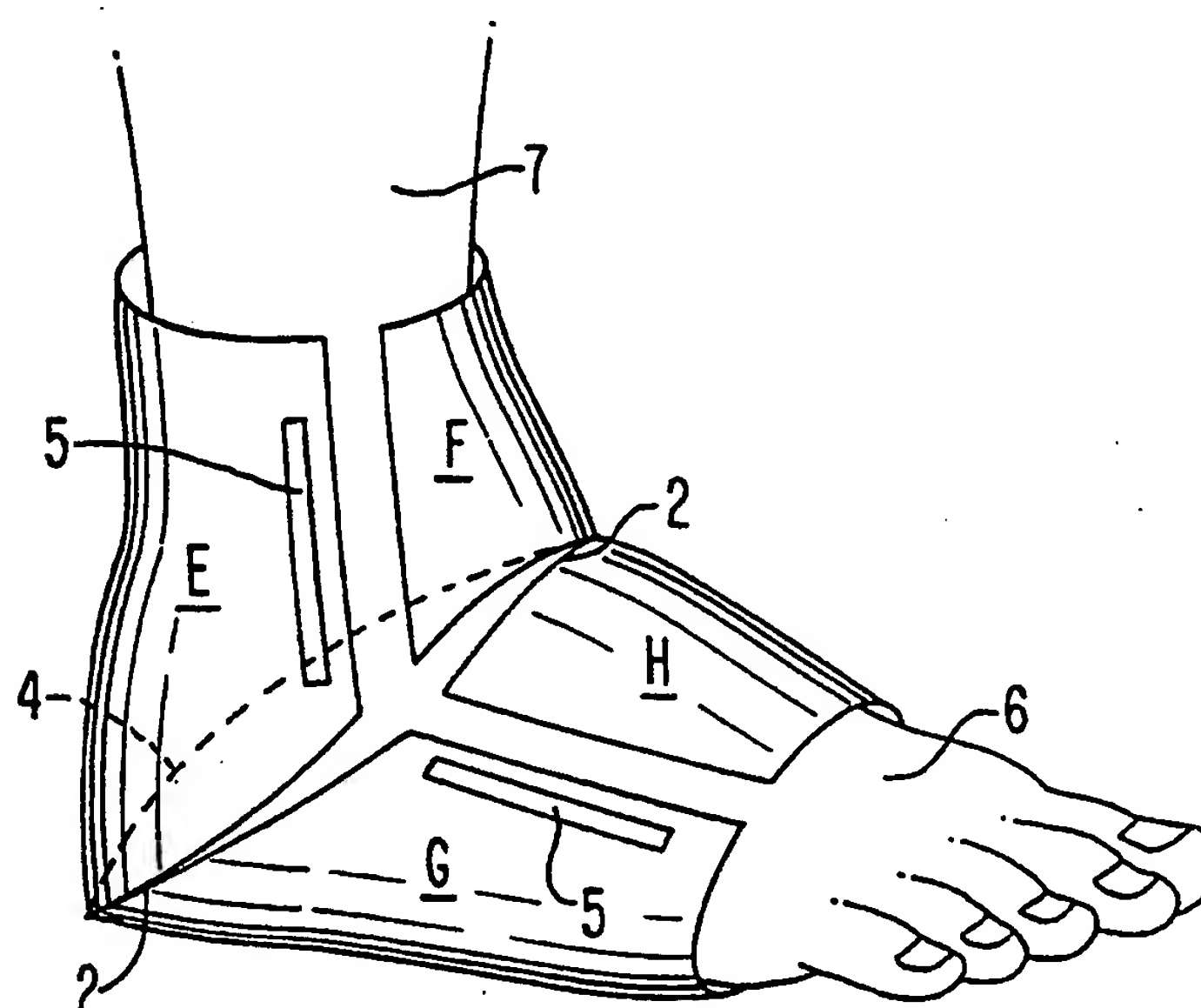


FIG. 1A



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FIG. 2

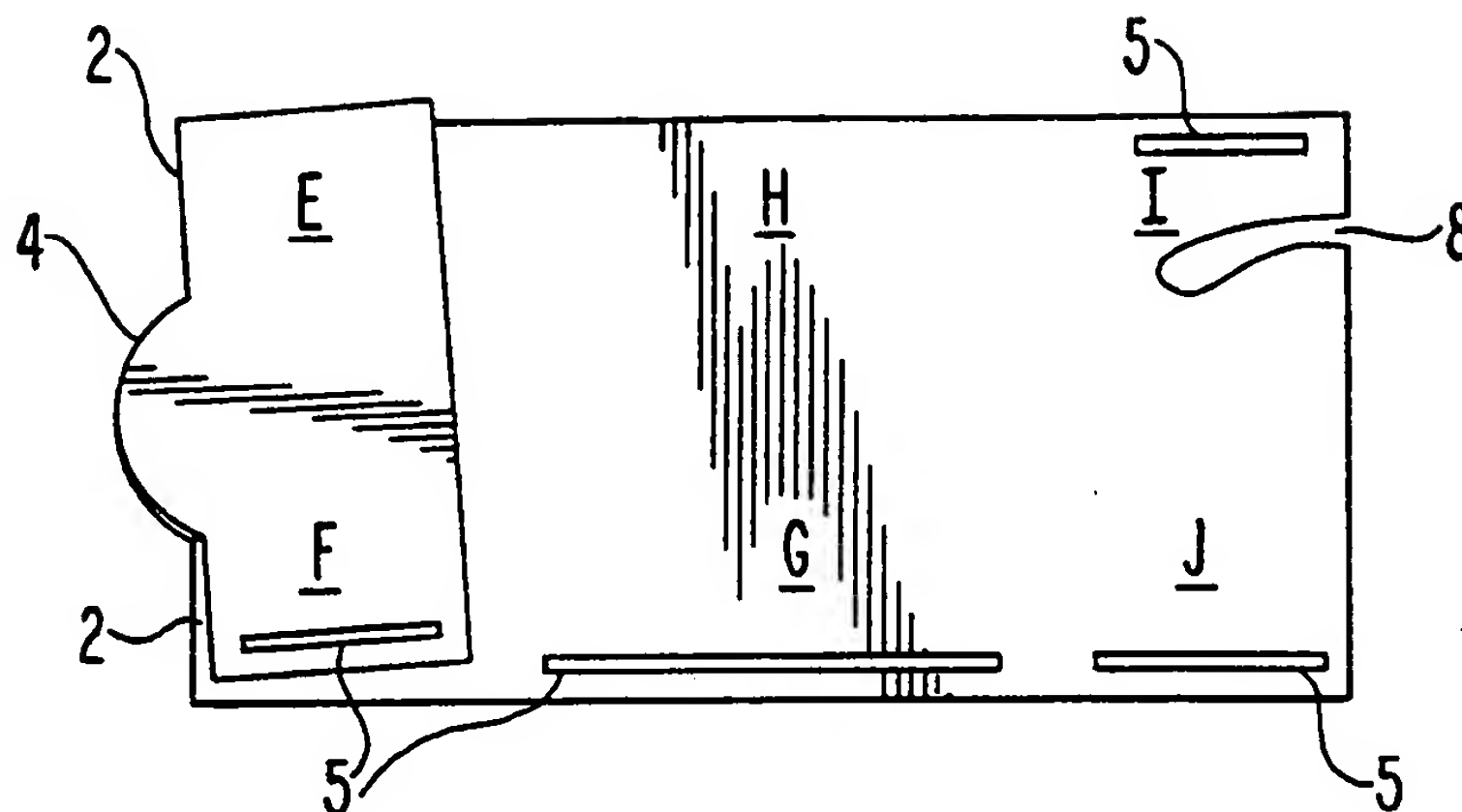
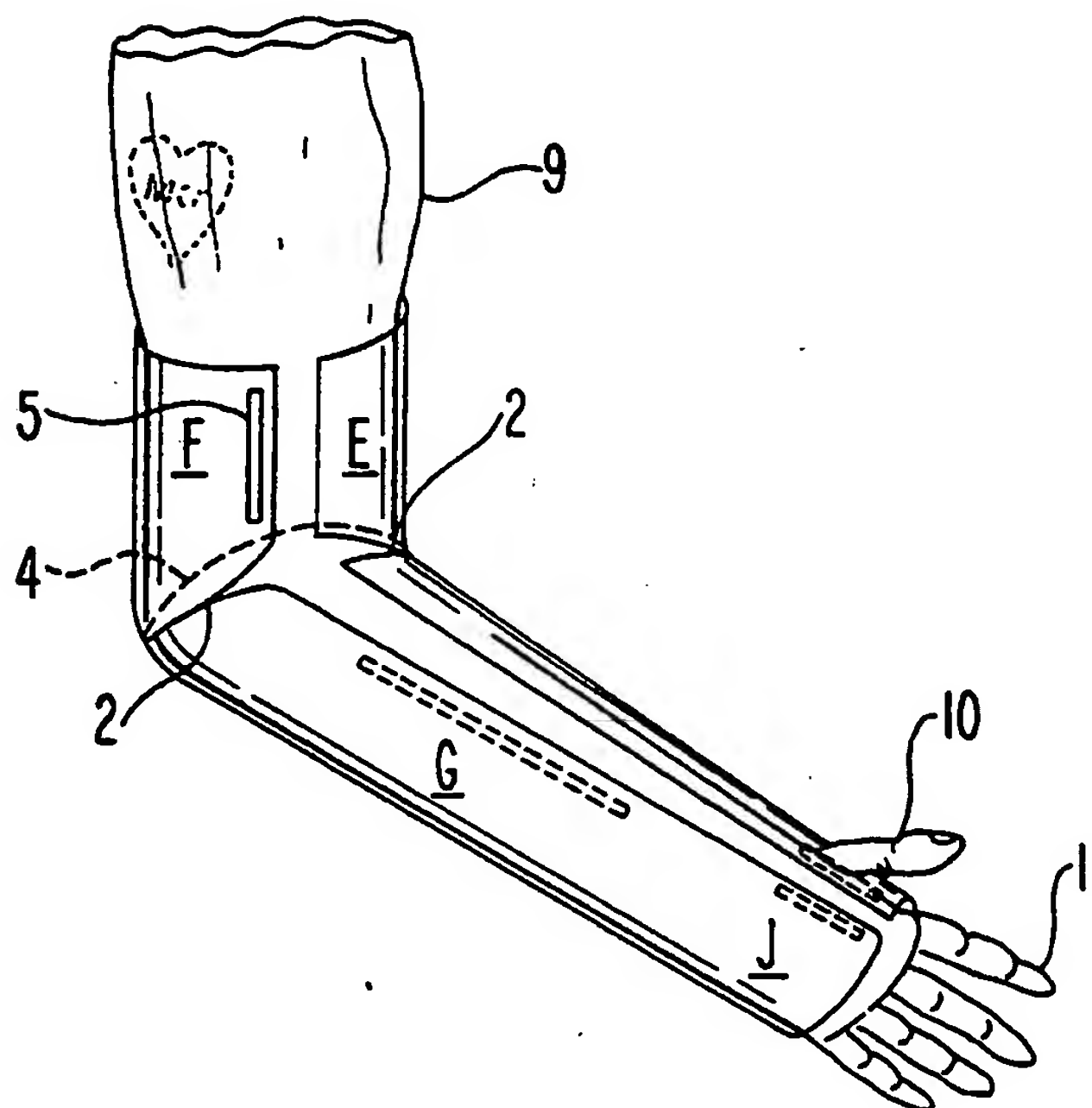


FIG. 2A



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FIG. 3

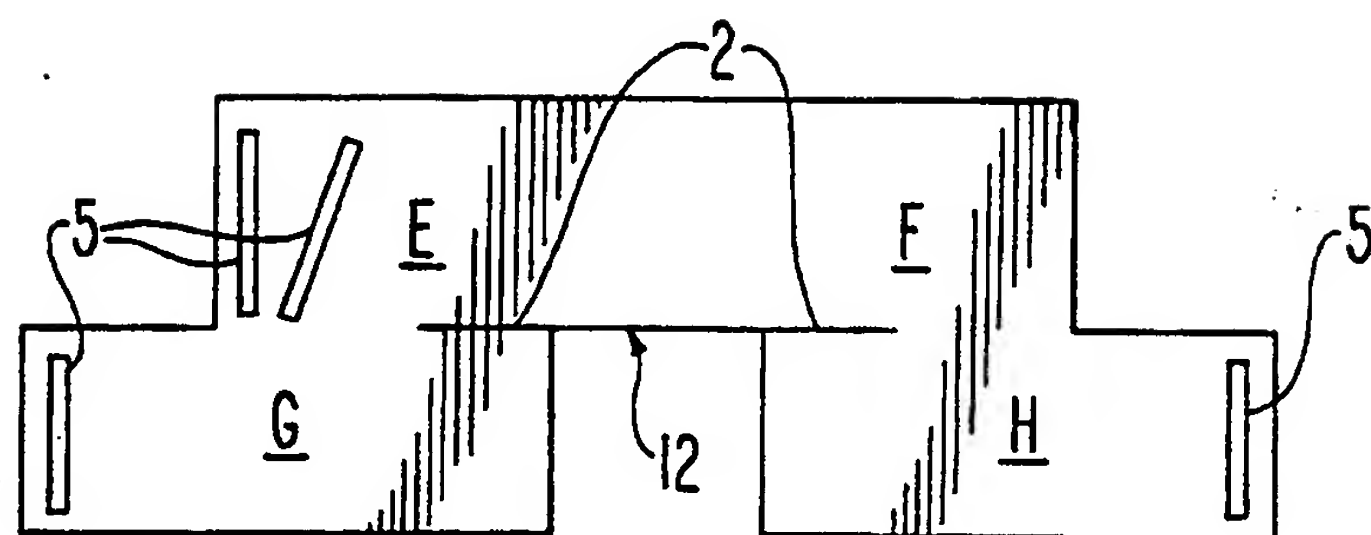


FIG. 3A

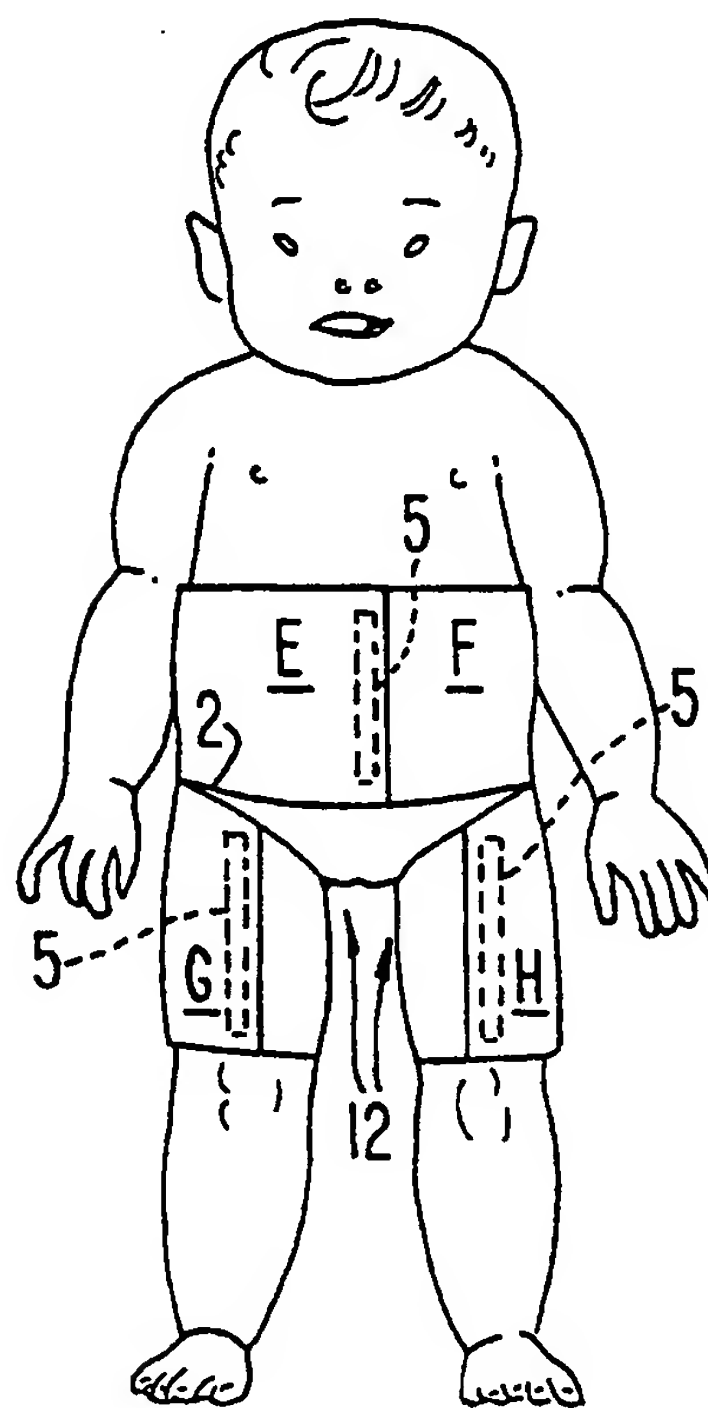


FIG. 4

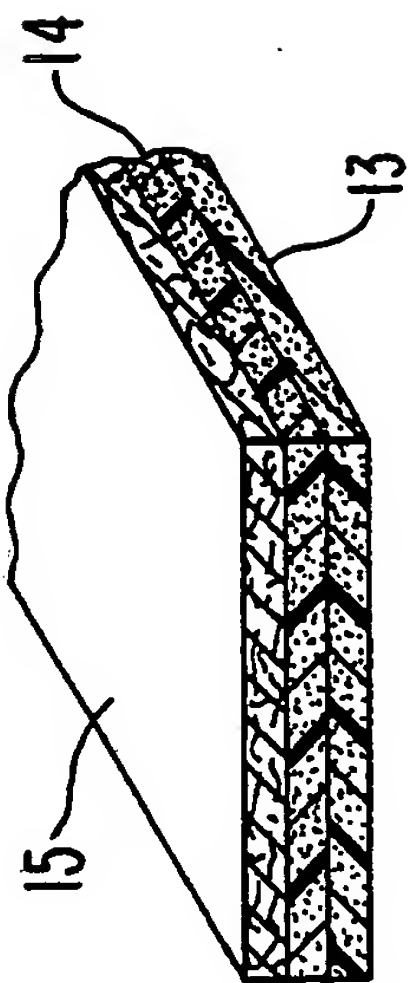


FIG. 5

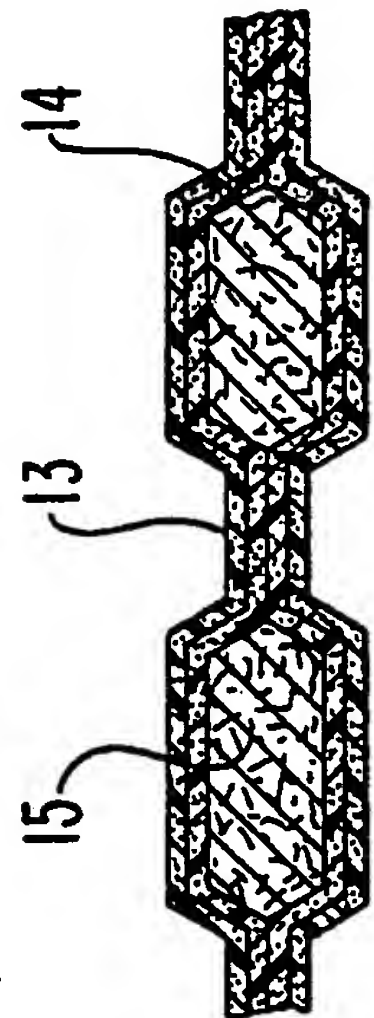


FIG. 6

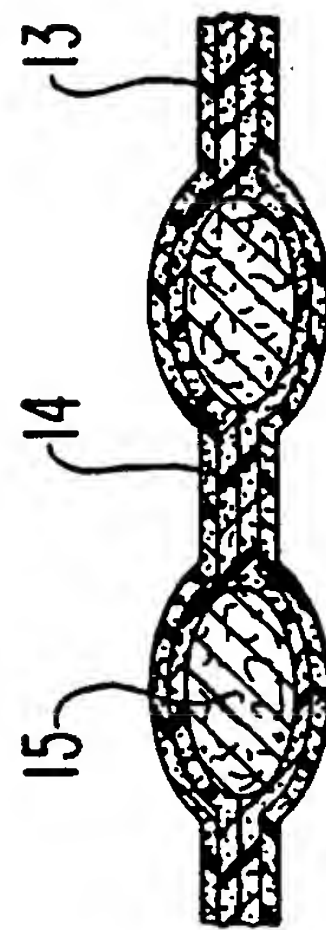
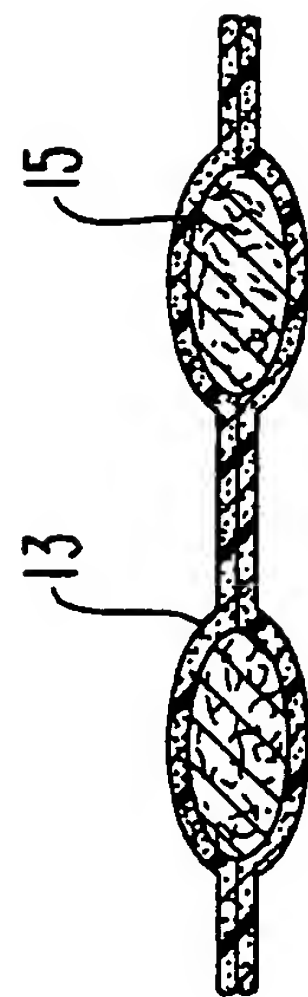
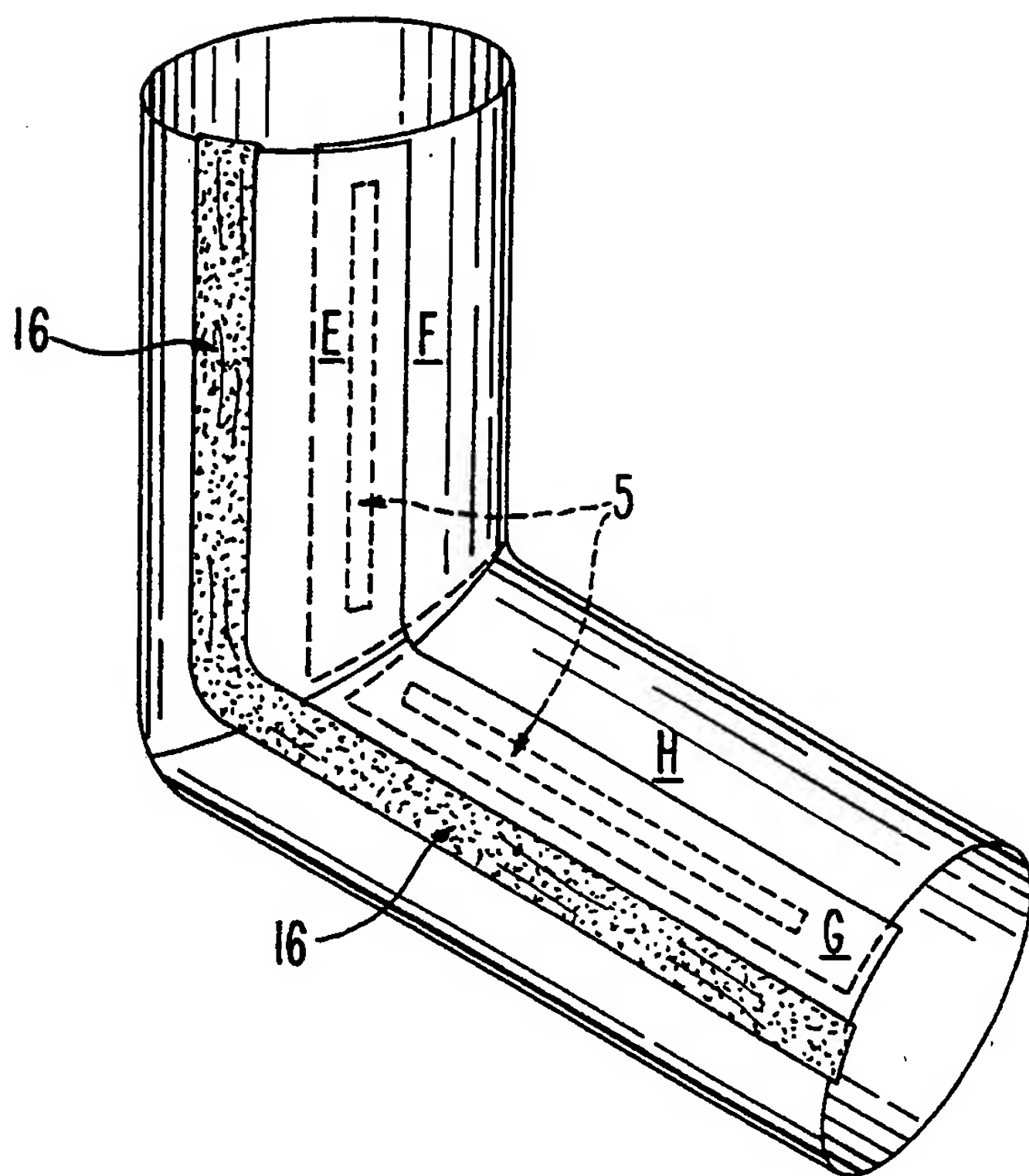


FIG. 7



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FIG. 8

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 92/10051

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F13/04

II. FIELDS SEARCHEDMinimum Documentation Searched⁷

Classification System

Classification Symbols

Int.Cl. 5

A61F

Documentation Searched other than Minimum Documentation
to the extent that such Documents are included in the Fields Searched⁸**III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹**

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y A	EP,A,0 397 998 (W.L.GORE & ASSOCIATES) 22 November 1990 see column 4, line 21 - line 46 see column 6, line 12 - line 21 see figures 3,5 ---	1,3-4,6, 9-13 5
Y A	US,A,4 494 536 (J.F.LATENSER) 22 January 1985 see column 2, line 20 - line 24 see column 3, line 46 - column 4, line 4 see figures 1-2 ---	1,3-4,6, 9-13 5
A	US,A,4 194 041 (R.W.GORE AND S.B.ALLEN JR.) 18 March 1980 cited in the application see the whole document ---	1-15
	-/--	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search

10 MARCH 1993

Date of Mailing of this International Search Report

02.04.93

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

NICE P.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,3 802 424 (A.E.NEWELL) 9 April 1974 see abstract; figures 1-3 -----	2

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9210051
SA 67438

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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10/03/93

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